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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,355	05/03/2001	Donald Morris	032775-047	6889

21839 7590 02/24/2003

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ALEXANDRIA, VA 22313-1404

EXAMINER

LAMBERTSON, DAVID A

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 02/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/847,355

Applicant(s)

MORRIS ET AL.

Examiner

David A Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of a reply, filed December 5, 2002 as Paper No. 9, to the previous Office Action. Amendments were made to the claims. Specifically, claim 25 was cancelled.

Claims 1-24 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, Paper No. 7, mailed August 24, 2002, that is not addressed in this action has been withdrawn.

Because this Office Action does not raise new rejections that are not based on amendments to the claims, this rejection is FINAL.

Priority

Applicant traverses the decision regarding the Examiner's denial of priority to US Application No. 60/201,990 as it regards claims 2-4. Applicant has provided an additional reference to more clearly identify that CD34 cells comprise hematopoietic stem cells that can be isolated from the blood or bone marrow, and that these specific cells were identified in the priority application. In light of the new information, the Examiner rescinds the denial of priority regarding claims 2-4.

Drawings

The Drawings have been approved by the Draftsperson.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This rejection is necessitated by amendment to the claims.**

Specifically, claim 1 (and all dependent claims) recites a newly added limitation of collecting the treated cellular composition “for future use”, where the quotation represents the newly added limitation. This limitation is indefinite because it does not clearly set forth the metes and bounds of the claim as it is unclear what the future use of the treated cellular composition is. As a result, claim 1 (and all dependent claims) is indefinite under 35 USC 112, second paragraph.

In addition, amended claim 1 (and all dependent claims) is unclear because applicants appear to be claiming a method of producing a cellular composition and a method for “future use” of the composition prepared by the recited method. The claim as originally set forth is drawn to a method of preparing a cellular composition. However, the newly added limitation sets forth a use of the composition, and does not refer to a method of making the composition. Thus, the claim is indefinite because it is unclear if the method is directed to a method of making the cellular composition or a method of using the cellular composition.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-24 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for selectively removing neoplastic cells with hyperactive-ras pathways, defective-p53 alleles (or a deletion of p53), and suppressed immune responsiveness, does not reasonably provide enablement for selectively removing any neoplastic cell. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. **This rejection is maintained for the reasons set forth in the previous Office Action, mailed August 24, 2002.**

Response to Arguments Concerning Rejections Under 35 USC 112, First Paragraph

Applicant's arguments filed December 5, 2002 as Paper No. 9 have been fully considered but they are not persuasive.

Applicant has attempted to overcome the scope of enablement rejection by amending the claim to read on a method "wherein the virus is capable of selectively killing the neoplastic cells." Applicant also points to examples 1 and 2 in the instant specification to indicate that all neoplastic cells are susceptible to the claimed method. These arguments are not sufficient to overcome the enablement rejection because they do not satisfy the criteria set forth in the Wands factors.

As indicated in the previous Office Action, the **scope of the invention** is very broad and encompasses all types of neoplastic cells. However, it is known by applicant (evidenced by the citation of relevant passages in the disclosure of the instant application

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and the inclusion of pertinent references in the information disclosure statement) that not all neoplastic cells fall into the categories for which applicant's methods are known to be effective. Stating "wherein the virus is capable of selectively killing the neoplastic cells" does not satisfy the scope requirement because the claim still reads on all neoplastic cells, and does not clearly indicate the subject matter for which the specification is enabling (neoplastic cells with hyperactive ras pathways, defective p53 alleles (or a deletion of p53), and suppressed immune responsiveness). Furthermore, Examples 1 and 2, specifically recited by applicant in their arguments, consider only three types of cancer cells, MCF7, SKBR3 and MDA MB 468 cells; these cells appear to be cancerous as a result of hyper-activated ras-pathways, and do not increase the scope of the invention as applicant's claim, absent evidence to the contrary. It therefore remains **unpredictable** from both the **state of the art, level of skill in the art** and the instant specification **(guidance and working examples provided by applicant)** how all neoplastic cells will behave in the method of the instant invention, for the reasons set forth in the previous Office Action. Therefore the skilled artisan would be required to practice undue trial and error experimentation with no predictability of success in order to determine if the invention could be used with respect to all neoplastic cells, even in light of the amendments to the claims and applicant's arguments.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed.

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Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8 and 24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 and 21 of copending Application No. 09/847,356 (Patent Application No. US 2002/0006398 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are genus claims which would be anticipated by the specific claims reciting a reovirus because it is obvious that a reovirus is a virus.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. **This rejection is maintained for the reasons set forth in the previous Office Action, mailed August 24, 2002.**

Response to Arguments Concerning Rejections Under Double Patenting

Applicant is required to submit a terminal disclaimer prior to any indication of allowable subject matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 9-11, 13-15 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by McCormick (WO 94/18992) or McCormick (US Patent No. 5,801,029).

This rejection is maintained for the reasons set forth in the previous Office Action, mailed August 24, 2002.

Response to Arguments Concerning Rejections Under 35 USC 102

Applicant's arguments filed December 5, 2002 as Paper No. 9 have been fully considered but they are not persuasive. Applicant appears to have amended the claims to indicate a method for preparing a composition of cells with a reduced amount of neoplastic cells for future use, with the intention of arguing that the claims are no longer anticipated by the McCormick references as a result of this added limitation. This argument is not found persuasive for the following reasons:

The recitation that the cells are to be collected for "future use" does not render patentable distinction upon the claims because the intended use does not contribute any structural characteristics to the compound that has been made by the claimed method. The claims are drawn to a method of making the cellular composition by selectively killing neoplastic cells with a virus, and are not drawn to a method of using the cells. Therefore, the recitation of collecting the cells for "future use" represents an intended use of the cells that have been made by the claimed method, and is irrelevant in light of the claimed invention. The composition that is made by the method is not patentably distinct from the composition made by the methods recited in the McCormick references, and the

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methods taught in both references anticipate the method of the instant invention. As a result, the rejection is maintained in light of the amendments to the claims and applicant's arguments.

In conclusion, the applicant has not obviated the previous rejection because the recitation of an intended use of the product made by the claimed method does not offer any patentable distinction to the method of producing the cellular composition. Therefore, the limitations of the claimed invention are still taught by the McCormick references, and the rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCormick (both WO 94/18992 and US Patent No. 5,801,029) in view of Lee et al. (US Patent No. 6,136,307). **This rejection is maintained for the reasons set forth in the previous Office Action, mailed August 24, 2002.**

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over McCormick (both WO 94/18992 and US Patent No. 5,801,029) in view of Lee et al. (US Patent No. 6,136,307) as applied to claims 2-6 and 8 above, and further in view of

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Bensinger (Bone Marrow Trans. 21: 113-115). **This rejection is maintained for the reasons set forth in the previous Office Action, mailed August 24, 2002.**

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over McCormick (both WO 94/18992 and US Patent No. 5,801,029) in view of Strong et al., (EMBO J. 17(12): 3351-3362 (1998)). **This rejection is maintained for the reasons set forth in the previous Office Action, mailed August 24, 2002.**

Claims 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCormick (both WO 94/18992 and US Patent No. 5,801,029) in view of Stojdl et al. (Nature Medicine 6(7): 821-825 (2000)). **This rejection is maintained for the reasons set forth in the previous Office Action, mailed August 24, 2002.**

Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCormick (both WO 94/18992 and US Patent No. 5,801,029) in view of Stewart et al. (Bone Marrow Trans. 23: 111-117 (1999)). **This rejection is maintained for the reasons set forth in the previous Office Action, mailed August 24, 2002.**

Response to Arguments Concerning Rejections Under 35 USC 103

Applicant's arguments filed December 5, 2002 as Paper No. 9 have been fully considered but they are not persuasive. Applicant appears to have amended the claims to indicate a method for preparing a composition of cells with a reduced amount of neoplastic cells for future use, with the intention of arguing that the claims are no longer

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anticipated by the McCormick references as a result of this added limitation, therefore they cannot be found obvious in view of the secondary references because the primary reference does not teach all of the elements of the claims; furthermore, there can be no motivation to combine the references in light of the fact that all of the elements of the claim have not been taught. This argument, which applies to each of the claims rejected under 35 USC 103(a), is not found persuasive for the following reasons:

First, the recitation that the cells are to be collected for "future use" does not render patentable distinction upon the claims because the intended use does not contribute any structural characteristics to the compound that has been made by the claimed method. The claims are drawn to a method of making the cellular composition by selectively killing neoplastic cells with a virus, and are not drawn to a method of using the cells. Therefore, the recitation of collecting the cells for "future use" represents an intended use of the cells that have been made by the claimed method, and is irrelevant in light of the claimed invention. The composition that is made by the method is not patentably distinct from the composition made by the methods recited in the McCormick references, and the methods taught in both references anticipate the method of the instant invention. As a result, the rejection under McCormick is maintained in light of the amendments to the claims and applicant's arguments because McCormick still teaches the relevant limitations of the claims. Therefore, the motivation to combine the references as originally presented, which has not been traversed in applicant's response, is still valid with respect to the claims as they are currently presented because McCormick does indeed teach all of the relevant claim limitations.

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In addition, applicant argues that the rejection of claim 7 concerning McCormick in view of Bensinger is invalid because Bensinger teaches away from the invention by questioning the wisdom of purging, stating that this rejection involves impermissible hindsight. Once again, applicant is reminded of the difference between the "intended use" of the cells, and the actual claimed invention of the method of selectively killing neoplastic cells to produce a "purged" cellular composition. While Bensinger questions the efficacy of the transplantation process and the potentially harmful effects of purged cells in the form of grafts, the reference does not question the purging of cells to reduce the number of neoplastic cells in a mixed cellular composition. Therefore, Bensinger does not question the method as claimed in the instant message, but the intended use of the composition that is made by the claimed invention. As a result, applicant's argument that the invention is made obvious only by impermissible hindsight is not found persuasive, and the rejection is maintained.

In conclusion, the applicant has not obviated the previous rejection because the recitation of an intended use of the product made by the claimed does not offer any patentable distinction to the method of producing the cellular composition. In addition, there is no need to derive motivation for the intended use because the intended use does not render any patentable distinction to the claimed method. Therefore, the limitations of the claimed invention are still taught by the McCormick references, and the motivation to combine the McCormick references with the Lee, Bensinger, Strong, Stojdl and Stewart references as presented in the previous Office Action (which have not been traversed) is sufficient to maintain the rejections.

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Allowable Subject Matter

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

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305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson
February 20, 2003

DAVID GUZO
PRIMARY EXAMINER
David Guzo
